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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: Joel S. Hochman, et al

Ser. No.: 10/007,393

Filed: October 26, 2001

For: SYSTEM AND METHOD FOR TRANSDUCING, SENSING OR AFFECTING VAGINAL OR BODY CONDITIONS, AND/OR STIMULATING PERINEAL MUSCULATURE AND NERVES USING 2-WAY WIRELESS COMMUNICATIONS

Examiner: Charles A. Marmor

Group: 3738

Commissioner for Patents
PO Box 1450
Alexandria VA 22313

DECLARATION TO SUPPORT THE NON-APPLICABILITY OF THE GUICE PATENT

I, Christopher J. Jayne, MD, declare as follows:

1. I am a Graduate with Honors from Buffalo School of Medicine, Buffalo New York, completed a residency in Obstetrics and Gynecology with Honors at Baylor College of Medicine, Houston Texas. I am Board Certified and a Fellow of the American College of Obstetricians and Gynecologists, and a Certified Sex Counselor by the American Association of Sex Educators Counselors and Therapists. I am the Medical Director of The Center for Women's Sexual Health at the Texas Medical Center in Houston Texas. I am a member of the Clinical Faculty at the Baylor College of Medicine in Houston Texas.
2. I am familiar with the subject matter of the above-identified application. In addition, I have carefully studied U.S. Patent Publication 2002/0010390, Guice, et al.

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Board Certified OB/GYN • AACICT Certified Sex Counselor

PAGE 6/8 * RCVD AT 11/30/2004 6:50:34 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-1/3 * DNI:8729306 * CSID:15052863524 * DURATION (mm:ss):02:32

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3. Based on my knowledge and expertise, I hereby state that one of ordinary skill in the art would not consider the Guice reference when trying to provide a system and method for transducing vaginal conditions, affecting vaginal or body conditions, and stimulating perineal musculature and nerves.
4. In particular, one of ordinary skill in the art would not look to Guice for any teaching or suggestion with respect to how to use or configure a device that is intended to be temporarily, i.e. in a non-implanted manner, inserted into a human vagina. Guice is clearly limited to use in animals, which is very understandable given the significant anatomical differences between the vaginas of animals, and especially cows, and those of humans. This is supported by FDA standards and regulations and safety concerns that define implants, as will be discussed below.
5. Guice, for example in [0179], makes it clear that his device is adapted to be compressed and then expanded to keep the device in place in an ear canal or other cavity of an animal. Guice even suggests adhesive. A tool is needed to be able to install and remove the device from the animal.
6. In the medical and veterinary fields, the device of the above-identified application is not an implant. In contrast, the device of Guice must be considered an implant, and this is also true under FDA standards. Thus, the device of Guice is in no way comparable to the temporarily insertable device of the above-identified application. Guice itself stresses that his device is a true implant. He furthermore refutes the use on non-implanted devices, as discussed, for example, in [34]. This is in large part due to the aforementioned differences in the anatomy of humans and animals, which requires that the device of Guice, in order to be effective, must be

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implanted in the animal being monitored. Furthermore, as mentioned above, pursuant to FDA standards and definitions, the Guice device is an implant whereas the device of the above-identified application is not, as confirmed by the FDA device approval letter issued to Athena.

7. In conclusion, the Guice device is entirely unsuitable for human vaginal use, and one of ordinary skill in the art would not consider the Guice reference for any teaching or suggestion with regard to the configuration of a device that is to be temporarily inserted into the human vagina.
8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of this application, the patent which issues thereon, or any patent to which this verified statement is directed.

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Date